

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

IN RE: NIASPAN ANTITRUST  
LITIGATION

WALGREEN CO., THE KROGER CO.,  
SAFEWAY INC., HEB GROCERY  
COMPANY L.P. and ALBERTSON'S LLC,

Plaintiffs,

vs.

ABBOTT LABORATORIES, ABBVIE INC.,  
TEVA PHARMACEUTICALS USA, INC.,  
TEVA PHARMACEUTICALS  
INDUSTRIES, LTD., TEVA WOMEN'S  
HEALTH, INC. f/k/a DURAMED  
PHARMACEUTICALS INC., DURAMED  
PHARMACEUTICALS SALES CORP. and  
BARR PHARMACEUTICALS, INC.,

Defendants.

MDL DOCKET NO. 2460  
MASTER FILE NO. 13-MD-2460

Civil Action No. \_\_\_\_\_

JURY TRIAL DEMANDED

**COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiffs Walgreen Co., The Kroger Co., Safeway Inc., HEB Grocery Company L.P. and Albertson's LLC bring this civil action against Defendants Abbott Laboratories, AbbVie, Inc. ("AbbVie" and, together with Abbott Laboratories, "Abbott"), Teva Pharmaceuticals, USA, Inc., Teva Pharmaceuticals Industries, Ltd., Teva Women's Health, Inc. f/k/a Duramed Pharmaceuticals, Inc. ("Duramed"), Duramed Pharmaceuticals Sales Corp. ("DPSC" and, together with the prior three named Defendants, "Teva") and Barr Pharmaceuticals, Inc. ("Barr") under the antitrust laws of the United States. For their Complaint, Plaintiffs allege as follows:

## **I. INTRODUCTION**

1. This is a civil antitrust action seeking treble damages and other relief arising out of Defendants' unlawful exclusion of generic competition to the brand-name drug Niaspan, which is extended-release niacin, a form of vitamin B used to treat lipid disorders. Niacin pills have been used since the 1930s and extended-release niacin has been sold as a prescription drug under the brand name Niaspan since 1997, first by Kos Pharmaceuticals, Inc. ("Kos") and later by Abbott and AbbVie, following various corporate mergers and restructuring. Although the first of several would-be generic competitors began applying to market generic extended-release niacin in October 2001, no generic competitor entered the market until September 2013, nearly twelve years later.

2. The unlawful scheme described below caused that delay. In 2005, Kos colluded with would-be generic competitor Barr and illegally delayed generic entry by paying Barr: (a) not to enter the market until September 20, 2013; and (b) to drop challenges to Kos's patents that ostensibly covered Niaspan. Kos's successors, Abbott and AbbVie, and Barr's successor, Teva, continued this illegal collusion and unreasonable restraint of trade in the market for extended-release niacin, all at the expense of Niaspan purchasers. Every month of delay of generic competition allowed Kos and its successors to preserve millions of dollars in monopoly profits from the sale of Niaspan without generic competition and allowed Barr and its successor to share in those profits by pocketing millions of dollars from Kos for agreeing to delay bringing generic extended-release niacin to market.

3. Beginning in early 2002, after Barr became the first generic manufacturer to seek approval from the Food and Drug Administration ("FDA") to market generic extended-release niacin, Kos sued Barr and accused it of infringing several patents ostensibly covering Niaspan. These lawsuits automatically triggered a thirty-month stay of FDA approval, meaning that

regardless of the merits of the patent infringement case, the FDA could not grant final approval to Barr to launch its generic product until March 31, 2005. And foreclosing Barr from launching also foreclosed all other generic manufacturers; as the first manufacturer to seek approval for generic extended-release niacin, Barr was entitled to 180 days of market exclusivity, without competition from other generic manufacturers, once it actually launched its product.

4. Between early 2002 and early 2005, while the thirty-month stay was in effect, Barr fought the patent infringement actions and prepared to bring its generic extended-release niacin to market to compete with Niacin. In March 2005, Barr was ready. Barr had received tentative approval from the FDA for three different strengths of extended-release niacin in mid-2003, with final approval being subject only to expiration of the thirty-month stay. In the months and weeks leading up to March 2005, Barr began accumulating inventory that it would need to fill orders for its product as soon as the launch occurred. All Barr needed was final FDA approval.

5. During this time, the patent litigation continued. Launching before the conclusion of patent litigation under some circumstances poses risks; if the court finds the relevant patent(s) valid, enforceable and infringed, the generic company may face substantial financial exposure from selling an infringing product. But Barr was so certain that it would prevail that Barr planned to launch its generic extended-release niacin as soon as the FDA gave the final green light, notwithstanding the pending patent litigation.

6. Barr expected the green light from the FDA in April 2005. And Barr was correct: on April 26, 2005, the FDA granted final approval for three strengths of Barr's generic extended-release niacin.

7. Barr was set to go—and competition would have commenced—but for one thing: days earlier, and not coincidentally, Kos and Barr colluded to forestall generic competition and maintain Kos’s monopoly at the expense of Niaspan purchasers. Rather than face one or more less expensive generics in the market and suffer the reduction in Niaspan sales and profits such competition would have caused, Kos paid Barr to stay off the market for eight years. Kos’s payments to Barr took two primary forms: cash and an agreement not to launch a competing “authorized generic” version of Niaspan when Barr eventually launched its generic in 2013. Barr accepted the payments, worth hundreds of millions of dollars, and agreed not to compete.

8. The scheme worked exactly as planned. Neither Barr nor any other generic competitor sold generic extended-release niacin until on or about September 20, 2013, far later than would have occurred absent Defendants’ unlawful agreement.

9. Had Barr (or its successor, Teva) launched a generic version of Niaspan at any time before September 20, 2013, extended-release niacin would have been sold at lower prices than the prices at which Kos/Abbott/AbbVie actually sold branded Niaspan, and Plaintiffs would have paid lower prices than they actually paid.

10. Had Barr launched earlier than September 20, 2013, whether at risk, via a payment-free settlement with an earlier entry date or after prevailing in the patent litigation, other generic manufacturers with applications for approval to sell generic equivalents of Niaspan would have been permitted to launch their own products following the lapse of Barr’s 180-day exclusivity period. By delaying Barr’s launch until September 20, 2013, Kos and Barr sought to prevent, and have succeeded in preventing, other generic competitors from launching until 2014.

11. Plaintiffs are direct purchasers or assignees of direct purchasers of Niaspan and are included in the proposed class definition in actions currently pending in this Court as part of

*In re Niaspan Antitrust Litigation*, MDL Docket No. 2460. The limitations period applicable to Plaintiffs' claims has been tolled since the filing of the first class action on behalf of direct purchasers of Niaspan.

## **II. THE PARTIES**

12. Plaintiff Walgreen Co. ("Walgreen") is an Illinois corporation having its principal place of business at 200 Wilmot Road, Deerfield, Illinois 60015. Walgreen owns and operates retail stores in several states at which it dispenses prescription drugs, including Niaspan, to the public. Walgreen brings this action in its own behalf and as the assignee of Cardinal Health, Inc. ("Cardinal"), a pharmaceutical wholesaler, which during the relevant period purchased Niaspan directly from Kos or its successor for resale to Walgreen and which has assigned its claims arising out of those purchases to Walgreen. In addition, Walgreen is contractually entitled to a second assignment from AmerisourceBergen Drug Corporation ("ABDC"), another pharmaceutical wholesaler, which during the relevant period purchased Niaspan directly from Kos or its successor for resale to Walgreen. Walgreen intends to include purchases made through ABDC in its damage claim when it obtains that assignment.

13. Plaintiff The Kroger Co. ("Kroger") is an Ohio corporation having its principal place of business at 1014 Vine Street, Cincinnati, Ohio 45202. Kroger owns and operates retail stores in several states at which it dispenses prescription drugs, including Niaspan, to the public. Kroger brings this action in its own behalf and as the assignee of Cardinal, which during the relevant period purchased Niaspan directly from Kos or its successor for resale to Kroger and which has assigned its claims arising out of those purchases to Kroger.

14. Plaintiff Safeway Inc. ("Safeway") is a Delaware corporation having its principal place of business at 5918 Stoneridge Mall Road, Pleasanton, California 94588. Safeway owns and operates retail stores in several states at which it dispenses prescription drugs, including

Niaspan, to the public. Safeway brings this action in its own behalf and as the assignee of Cardinal, which during the relevant period purchased Niaspan directly from Kos or its successor for resale to Safeway and which has assigned its claim arising out of those purchases to Safeway.

15. Plaintiff HEB Grocery Company L.P. (“HEB”) is a Texas limited partnership having its principal place of business at 646 South Main Avenue, San Antonio, Texas 78204. HEB owns and operates retail stores at which it dispenses prescription drugs, including Niaspan, to the public. HEB brings this action in its own behalf and as the assignee of Cardinal and McKesson Corporation (“McKesson”), another pharmaceutical wholesaler, which during the relevant period purchased Niaspan directly from Kos or its successor for resale to HEB and which have assigned their claims arising out of those purchases to HEB.

16. Plaintiff Albertson’s LLC (“Albertson’s”) is a Delaware limited liability company having its principal place of business at 250 Parkcenter Boulevard, Boise, Idaho 83706. Albertson’s owns and operates retail stores in several states at which it dispenses prescription drugs, including Niaspan, to the public. Albertson’s brings this action in its own behalf and as the assignee of McKesson, which during the relevant period purchased Niaspan directly from Kos or its successor for resale to Albertson’s and which has assigned a portion of its claims arising out of those purchases to Albertson’s.

17. Defendant Abbott Laboratories is an Illinois corporation with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois. Abbott purchased Kos Pharmaceuticals, Inc. in 2006. On or about January 1, 2013, Abbott spun off most of its pharmaceutical operations to AbbVie, Inc.

18. Defendant AbbVie Inc. is a Delaware corporation with its principal place of business at 1 North Waukegan Road, North Chicago, Illinois.

19. Defendant Teva Pharmaceuticals USA, Inc. is a Delaware corporation with its principal place of business at 1090 Horsham Road, P. O. Box 1090, North Wales, Pennsylvania.

20. Defendant Teva Pharmaceutical Industries, Ltd. is an Israeli corporation with its principal place of business at 5 Basel Street, P. O. Box 3190, Petach Tikva, Israel. Teva is a leading manufacturer of generic drugs and one of the largest sellers of generic drugs in the United States.

21. Prior to its acquisition by Teva in December 2008, Defendant Barr Pharmaceuticals Inc. was a Delaware corporation with its principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey. In December 2008, Barr Pharmaceuticals Inc. was acquired by Teva and became a wholly-owned subsidiary of Teva.

22. Defendant Duramed Pharmaceuticals Inc. is a Delaware corporation with its principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey. Until 2008, Duramed was a subsidiary of Barr. In 2008, when Teva purchased Barr, Duramed became a subsidiary of Teva. Duramed is now known as Teva Women's Health, Inc.

23. Defendant Duramed Pharmaceutical Sales Corp. is a Delaware corporation with its principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey. Until 2008, DPSC was a subsidiary of Barr. In 2008, when Teva purchased Barr, DPSC became a subsidiary of Teva.

24. Kos Pharmaceuticals, Inc. ("Kos") and its wholly-owned subsidiary Kos Life Sciences, Inc. were among the initiators of the unlawful scheme described in this complaint. Kos was a Florida corporation with its principal place of business at 1 Cedar Brook Drive, Cranbury, New Jersey. In 2006, Kos and Kos Life Sciences, Inc. were acquired by and merged into Abbott, which became the successor to all of their unlawful conduct described in this Complaint.



25. All of Defendants' actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Defendants.

### **III. JURISDICTION AND VENUE**

26. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26, to recover threefold damages, injunctive relief, costs of suit and reasonable attorneys' fees for the injuries sustained by Plaintiffs resulting from Defendants' unlawful foreclosure of the United States market for extended-release niacin. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1337(a).

27. Defendants transact business within this district and/or have an agent and/or can be found in this district. Venue is appropriate within this district under section 12 of the Clayton Act, 15 U.S.C. § 22, as well as 28 U.S.C. §1391(b) and (c) and 28 U.S.C. § 1407(a).

### **IV. OPERATIVE FACTS**

#### **A. Characteristics of the Prescription Pharmaceutical Marketplace**

28. The marketplace for the sale of prescription pharmaceutical products in the United States suffers from a significant imperfection that brand manufacturers can exploit in order to obtain or maintain market power in the sale of a particular pharmaceutical composition. Markets function best when the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person has both the payment obligation and the choice of products, the price of the product plays an appropriate role in the person's



choice of products and, consequently, the manufacturers have an appropriate incentive to lower the prices of their products.

29. The pharmaceutical marketplace, however, is characterized by a “disconnect” between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Niaspan, to patients without a prescription written by a doctor. The prohibition on dispensing certain products without a prescription introduces a disconnect between the payment obligation and the product selection. The patient (and in most cases his or her insurer) has the obligation to pay for the pharmaceutical product, but the patient’s doctor chooses which product the patient will buy.

30. Abbott and other brand manufacturers exploit this price disconnect by employing large forces of sales representatives to visit doctors’ offices and persuade them to prescribe the manufacturer’s products. These sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are insensitive to price differences because they do not have to pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

31. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the price elasticity of demand – the extent to which unit sales go down when price goes up. This reduced price elasticity in turn gives brand manufacturers the ability to raise price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise price substantially above marginal cost is what economists and antitrust courts refer to as market power. The result of the market

imperfections and marketing practices described above is to allow brand manufacturers to gain and maintain market power with respect to many branded prescription pharmaceuticals.

**B. The Regulatory Structure for Approval of Generic Drugs and the Substitution of Generic Drugs for Brand Name Drugs**

32. Under the Federal Food, Drug, and Cosmetic Act (“FDCA”), manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application (“NDA”). 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

33. When the FDA approves a brand manufacturer’s NDA, the drug product is listed in an FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the “Orange Book.” The manufacturer may list in the Orange Book any patents that the manufacturer believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. The manufacturer may subsequently list in the Orange Book within thirty days of issuance any such patents issued after the FDA approves the NDA. 21 U.S.C. §§ 355(b)(1) & (c)(2).

34. The FDA relies completely on the brand manufacturer’s truthfulness about patent validity and applicability, as it does not have the resources or authority to verify the manufacturer’s patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

**C. The Hatch-Waxman Amendments**

35. The Hatch-Waxman Amendments (also “Hatch-Waxman”), enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need

for them to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application (“ANDA”). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer’s original NDA, and must further show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and is absorbed at the same rate and to the same extent as the brand drug—that is, that the generic drug is pharmaceutically equivalent and bioequivalent (together, “therapeutically equivalent”) to the brand drug. The FDA assigns generic drugs that are therapeutically equivalent to their brand-name counterpart an “AB” rating.

36. The FDCA and Hatch-Waxman Amendments operate on the presumption that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B).

37. Congress enacted the Hatch-Waxman Amendments to expedite the entry of legitimate (non-infringing) generic competitors, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers’ incentives to create new and innovative products.

38. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historic high profit margins for

brand manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generic drugs totaled \$21.6 billion; by 2009 total prescription drug revenue had soared to \$300 billion.

#### **D. Paragraph IV Certifications**

39. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

- i. that no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");
- ii. that the patent for the brand drug has expired (a "Paragraph II certification");
- iii. that the patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or
- iv. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

40. If a generic manufacturer files a Paragraph IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to market its

product. The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

41. As an incentive to spur manufacturers to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification typically gets a period of protection from competition from other generic versions of the drug. For Paragraph IV certifications made after December 2003, the first generic applicant receives 180 days of market exclusivity (unless some forfeiture event, like that discussed below, occurs). This means that the first approved generic is the only available generic for at least six months, which effectively creates a duopoly between the brand company and the first-filing generic during this period. This 180-day exclusivity period is extremely valuable to generic companies. While only one generic is on the market, the generic price, while lower than the branded price, is much higher than after multiple generic competitors enter the market. Generics are usually at least 25% less expensive than their brand name counterparts when there is a single generic competitor, but this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market. Being able to sell at the higher duopoly price for six months may be worth hundreds of millions of dollars.

42. Brand manufacturers can “game the system” by listing patents in the Orange Book (even if such patents are not eligible for listing) and suing any generic competitor that files an ANDA with a Paragraph IV certification (even if the competitor’s product does not actually infringe the listed patents) in order to delay final FDA approval of an ANDA for up to 30 months. That brand manufacturers often sue generics under Hatch-Waxman simply to delay generic competition—as opposed to enforcing a valid patent that is actually infringed by the generic—is demonstrated by the fact that generic firms have prevailed in Paragraph IV litigation,

by obtaining a judgment of invalidity or non-infringement or by the patent holder's voluntary dismissal, in cases involving 73% of the drug products studied.

43. The first generic applicant can help the brand manufacturer "game the system" by delaying not only its own market entry, but also the market entry of all other generic manufacturers. The first generic applicant, by agreeing not to begin marketing its generic drug, thereby delays the start of the 180-day period of generic market exclusivity, a tactic called exclusivity "parking." This tactic creates a "bottleneck" because later generic applicants cannot launch until the first generic applicant's 180-day exclusivity has elapsed or is forfeited.

#### **E. The Benefits of Generic Drugs**

44. Generic versions of brand name drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective, as their brand name counterparts. The only material difference between generic and brand name drugs is their price: generics are usually at least 25% less expensive than their brand name counterparts when there is a single generic competitor, and this discount typically increases to 80% (or more) when there are multiple generic competitors on the market for a given brand. The launch of a generic drug thus brings huge cost savings for all drug purchasers. The Federal Trade Commission ("FTC") estimates that about one year after market entry, the generic version takes over 90% of the brand's unit sales and sells for 15% of the price of the brand name product. As a result, competition from generic drugs is viewed by brand name drug companies such as Kos/Abbott/AbbVie as a grave threat to their bottom lines.

45. Due to the price differentials between brand and generic drugs, and other institutional features of the pharmaceutical industry, pharmacists liberally and substantially substitute for the generic version when presented with a prescription for the brand-name counterpart. Since passage of the Hatch-Waxman Amendments, every state has adopted

substitution laws that either require or permit pharmacies to substitute generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise by writing “dispense as written” or similar language on the prescription).

46. There is an incentive to choose the less expensive generic equivalent in every link in the prescription drug chain. Pharmaceutical wholesalers and retailers are able to acquire generic drugs at lower prices than the corresponding brand-name drug. Health insurers and patients also benefit from the lower prices that result from generic competition.

47. Until a generic version of the brand drug enters the market, there is no bioequivalent generic drug to substitute for and compete with the brand drug, and therefore the brand manufacturer can continue to profitably charge supracompetitive prices without losing sales. As a result, brand manufacturers, who are well aware of generics’ rapid erosion of their brand sales, have a strong incentive to delay the introduction of generic competition into the market, including by using tactics such as the agreement at issue here.

#### **F. The Impact of Authorized Generics**

48. The 180-day marketing exclusivity to which first-filer generics may be entitled does not prevent a brand manufacturer from marketing its own generic alternative to the brand drug during that 180-day period pursuant to its own approved NDA. Such an “authorized generic” is chemically identical to the brand drug, but is sold as a generic product through either the brand manufacturer’s subsidiary (if it has one) or through a third-party generic manufacturer. Competition from an authorized generic during the 180-day exclusivity period substantially reduces the price of both generic drugs and, in addition, forces the first-filer to share the generic sales made at those lower prices with the brand-name manufacturer. Both of these effects reduce the first-filer’s revenues and profits.



49. In its study, *Authorized Generic Drugs: Short-term Effects and Long-Term Impact* (August 2011) (the “FTC Study”), the Federal Trade Commission found that authorized generics capture a significant portion of sales, reducing the first-filer generic’s revenues by approximately 50% on average during the 180-day exclusivity period. The first-filing generic makes significantly less money when it faces competition from an authorized generic because (1) the authorized generic takes a large share of unit sales away from the first-filer; and (2) the presence of an additional generic in the market causes the price of both generic drugs to decrease.

50. Although first-filing generic manufacturers make significantly less money when they must compete with an authorized generic during the first 180 days, drug purchasers such as Plaintiffs benefit from the lower prices caused by competition between the authorized generic and the first-filing generic.

51. As a practical matter, authorized generics are the only means by which brand-name manufacturers engage in price competition with manufacturers of AB-rated generic drugs. Brand-name manufacturers generally do not reduce the price of their branded drug in response to the entry of an AB-rated generic. Instead, they either raise the price to extract higher prices from the small number of “brand-loyal” patients or, more typically, they continue to raise the price of the branded drug at the same intervals and at the same rate at which they raised the price of the drug prior to generic entry.

52. Given the significant negative impact of an authorized generic on the first-filing generic’s revenues, and given the absence of any other form of price competition from the branded manufacturer, a brand manufacturer’s agreement not to launch an authorized generic has tremendous value to the generic manufacturer. Brand manufacturers have used such agreements as a way to pay the first-filer to delay entering the market. Such non-competition agreements

deprive drug purchasers such as Plaintiffs of the lower prices resulting from two forms of competition: (1) among the branded and the generic products; and (2) between the generic products.

## **V. DEFENDANTS' ANTICOMPETITIVE SCHEME**

### **A. Niaspan accounted for the vast majority of Kos's revenues and profits.**

53. Niacin is vitamin B3. It was discovered in the late 1800s, appears naturally in many foods and started being sold as a dietary supplement in the United States beginning in the 1930s. In proper dosages, niacin will raise levels of HDL cholesterol ("good" cholesterol) in patients. However, at high levels, niacin causes a patient's skin to flush with redness and may also cause liver toxicity.

54. In the 1990s, Kos set out to develop a time-release version of niacin, which could (a) be marketed as a once-a-day therapy to boost HDL cholesterol in patients who needed treatment for cholesterol levels and (b) avoid the side effects associated with high dosages of niacin. Eventually, Kos developed Niaspan, a time-release version of niacin, which it intended to market as a brand name prescription drug. Importantly, Kos did not claim to have discovered that niacin reduces cholesterol (a fact that was documented in the 1950s), nor was it the first company to make a sustained release niacin formulation. Kos simply created a formulation that had a release rate that helped minimize or avoid certain side effects.

55. Kos was unable to patent the active ingredient in Niaspan because niacin was in the public domain. However, Kos sought and received seven patents to cover the formulation and use of Niaspan: Patent No. 6,080,428 (the '428 Patent); Patent No. 6,129,930 (the '930 Patent); Patent No. 6,406,715 (the '715 Patent); Patent No. 6,469,035 (the '035 Patent); Patent No. 6,676,967 (the '967 Patent); Patent No. 6,746,691 (the '691 Patent); Patent No. 6,818,229

(the '229 Patent). In addition, Kos purchased two more patents: Patent Nos. 5,126,145 and 5,268,181 (the '145 Patent and the '181 Patent).

56. Kos filed an NDA for Niaspan and received FDA approval on July 28, 1997 to market Niaspan for the treatment of mixed lipid disorders.

57. Over time, Kos submitted all nine of the above patents to the FDA for listing in the Orange Book.

58. In September of 1997, Kos went to market with Niaspan, eventually selling Niaspan in dosages of 500 mg, 750 mg, and 1000 mg. Niaspan was the only once-a-day prescription formulation of extended-release niacin available for treating mixed lipid disorders. Because of its unique position, doctors prescribed Niaspan often, and the drug garnered hundreds of millions of dollars in annual sales.

59. In the early years, sales of Niaspan made up the vast majority of Kos's sales revenue because Kos had no other significant drugs in its portfolio. As time went on, Kos began to sell other drugs, but Niaspan always accounted for a substantial portion of Kos's sales revenues. Specifically, in those early years:

- a. In 2001, Kos sold \$87 million of Niaspan - 100% of the company's sales revenue for the year.
- b. In 2002, Kos sold \$146 million of Niaspan - 84% of the company's sales revenue for the year.
- c. In 2003, Kos sold \$226 million of Niaspan - 77% of the company's sales revenue for the year.
- d. In 2004, Kos sold \$319 million of Niaspan - 64% of the company's sales revenue for the year.
- e. In 2005, Kos sold \$435 million of Niaspan - 57% of the company's sales revenue for the year.

60. Kos (and later Abbott and AbbVie) had market power with respect to Niaspan. Indeed, on several occasions during those early years, Kos reported that it was able to raise prices on Niaspan (even though costs were not increasing) while simultaneously increasing its sales volumes on the drug.

**B. Barr posed a competitive threat by preparing to bring a generic equivalent of Niaspan to market.**

61. After conducting extensive research and analysis regarding the patents that Kos had registered and legal due diligence concerning potential infringement or invalidity of Kos's patents, and spending over \$2.3 million in the process, Barr concluded that Kos's patents were invalid or unenforceable and/or that Barr's generic product would not infringe the patents. Accordingly, on October 2, 2001, Barr submitted ANDA 76-250 to the FDA, seeking approval to market a generic equivalent of the 1000 mg dosage of Niaspan.

62. On January 15, 2002, Barr sent Kos a Paragraph IV certification with respect to the listed patents covering Niaspan in a 1000 mg dosage. In that Paragraph IV certification, Barr stated that its proposed extended-release niacin, a generic version of Niaspan, would not infringe any of Kos's patents then listed in the Orange Book, that Kos's patents were invalid, and/or that Kos's patents were unenforceable. Barr was the first company to file such a certification. As the first ANDA filer to make a Paragraph IV certification, Barr expected that it was entitled to an exclusive 180-day period (as against other generic manufacturers) to market its generic extended-release niacin once the FDA approved the ANDA.

63. Kos immediately saw Barr as a competitive threat, and sought to thwart Barr's efforts to bring a generic equivalent of Niaspan to market. President and CEO Adrian Adams promised that Kos would "vigorously enforce [its] patent rights in order to protect Kos's cholesterol products, which [Kos has] effectively pioneered entirely on [its] own."

64. On March 4, 2002, Kos sued Barr in the United States District Court for the Southern District of New York (docketed as 02-cv-1683), alleging that Barr's proposed generic extended-release niacin and related Paragraph IV certification infringed upon the '428 Patent and the '930 Patent with respect to the 1000 mg dosage of Niaspan. By operation of law, the filing of that lawsuit triggered a thirty-month stay that prohibited the FDA from granting final approval to Barr to launch a generic equivalent of Niaspan.

65. In the months that followed, Kos filed two more patent infringement lawsuits against Barr relating to Niaspan.

66. On August 13, 2002, Kos filed a second patent infringement lawsuit against Barr in the United States District Court for the Southern District of New York (docketed as 02-cv-6409), this time alleging that Barr had infringed the '428 Patent and '930 Patent by filing ANDA 76-738 (with an accompanying a Paragraph IV certification) with respect to the 500 mg and 750 mg dosages of Niaspan.

67. On November 12, 2002, Kos filed a third patent infringement lawsuit against Barr in the United States District Court for the Southern District of New York (docketed as 02-cv-8995), this time alleging that Barr had infringed the '715 Patent by submitting a supplemental Paragraph IV certification (dated September 30, 2002) regarding Niaspan.

68. Those cases were all consolidated into one proceeding. Under the law as it existed at that time, each of those lawsuits triggered a new thirty-month stay, and the last of those thirty-month stays began to run on September 30, 2002 (the date of Barr's supplemental Paragraph IV certification). Thus, the FDA was stayed from granting Barr final approval for marketing any generic equivalent of Niaspan until March 31, 2005.

69. On March 26, 2004, Kos filed a fourth patent infringement lawsuit against Barr in the United States District Court for the Southern District of New York (docketed as 04-cv-1683), this time alleging that Barr had infringed the '967 Patent by filing Paragraph IV certifications with respect to Niaspan.

70. That fourth case was consolidated with the first three cases. In the consolidated proceeding, Barr filed counterclaims against Kos, seeking declaratory judgments that Barr's Paragraph IV certifications did not infringe any of the relevant patents held by Kos. Barr's counterclaims also sought rulings that those patents were invalid or otherwise unenforceable.

71. On September 3, 2004, Barr filed an action against Kos in the United States District Court for the Southern District of New York (docketed as 04-cv-7086), seeking a declaratory judgment that Barr was not infringing the '691 Patent and/or that the '691 Patent was invalid or otherwise unenforceable. This fifth lawsuit was also consolidated with the other pending patent infringement actions.

72. While the patent suits were pending, and while the thirty-month stay was still in place from the first three lawsuits, the FDA gave Barr tentative approval to proceed to market with its generic extended-release niacin. Barr received tentative approval for its 1000 mg product on May 9, 2003 and received tentative approval for its 500 mg and 750 mg products on June 13, 2003. Barr expected to receive final approval from the FDA shortly after the last of the thirty-month stays expired—that is, shortly after March 31, 2005. (Unless indicated otherwise, “Niaspan” or “extended-release niacin” refers to all of the strengths of the drug.)

73. The patent lawsuits continued for more than two years without any substantive rulings on the merits of the patent claims. The court issued no claim construction rulings and no

summary judgment rulings. On December 3, 2004, the court scheduled a trial for the consolidated cases for January of 2006.

**C. Barr prepared to launch a generic equivalent of Niaspan at-risk in the spring of 2005.**

74. As 2004 was drawing to a close, Barr was preparing to launch its generic extended-release niacin “at risk”: shortly after the thirty-month stay expired but before the patent litigation was resolved. Launching before resolution of the patent infringement litigation is considered “at risk” because the generic manufacturer can risk incurring substantial damages if the patent litigation results in a favorable ruling for the brand name manufacturer. A generic manufacturer must thus be sure of its patent footing to attempt an “at-risk” launch.

75. By the spring of 2005, Barr was ready, willing, and able to launch its generic extended-release niacin as soon as the FDA approved Barr’s ANDA. Reports concerning Barr’s anticipated impending at-risk launch caused Kos’s shares to drop 13% in December of 2004.

76. Barr’s at-risk launch would have brought a generic to market in the spring of 2005, without regard to the strength of the claims in the pending patent lawsuits, and without regard to the expiration dates on any of Kos’s patents. And Barr retained its 180-day exclusivity period, free from competition from other generic manufacturers.

77. Kos saw the prospect of an at-risk launch by Barr as a growing competitive threat and acted swiftly in response.

78. Kos began preparing to launch its own authorized generic version of Niaspan, which would (a) effectively deprive Barr of 180 days of exclusivity as the sole generic on the market and (b) replace some of Kos’s lost brand revenues with those from authorized generic sales. Kos began manufacturing this authorized generic version of Niaspan to have inventory on hand to sell as soon as Barr launched at risk. By the end of the first quarter of 2005, Kos had



accumulated substantial inventory for its authorized generic launch. Kos was prepared to launch, and would have launched, an authorized generic version of Niaspan in early 2005 if Barr had launched its generic extended-release niacin product at risk.

79. On March 7, 2005, Kos sought a preliminary injunction to prohibit Barr from proceeding with its at-risk launch of generic Niaspan. The court held a hearing on Kos's application for a preliminary injunction on March 18, 2005.

80. At the time of the March 18th hearing, Barr was ready to launch its generic equivalent of Niaspan and was accumulating inventory that it would need to fill orders for its generic product as soon as the launch occurred. Barr was waiting only for the FDA to issue final approval, which Barr expected to receive in April 2005.

81. But both Kos and Barr had enormous incentives to settle the patent infringement litigation and avoid competition. Niaspan constituted the vast majority of Kos's company-wide sales revenue from 2001 through 2005; losing a substantial portion of that revenue stream, as Kos would have if the patents were held by a court to be invalid, unenforceable, or not infringed, would have drastically affected Kos's profits. And without a substantial revenue stream from Niaspan, Abbott would have paid vastly less for Kos the next year. Kos, therefore, was desperate to settle the patent litigation with Barr. Even Barr acknowledged that the patent infringement litigation "was literally 'bet-the-company' for Kos because Niaspan provided over 80 percent of the company's profits to support its \$1.8 billion market capitalization."

82. Barr, too, desired to settle the patent litigation. Barr's profits during its 180-day exclusivity period would plummet if Kos had launched an authorized generic during that time, as Kos was preparing to do. The competition among multiple generics would have driven down the price of generic Niaspan. Once there are multiple generic versions of the same brand drug

available, the generic behaves like a commodity, with little to distinguish one generic from another except price. While such competitive generic sales are still profitable, it can be substantially more profitable to be paid by the brand company not to compete. Barr knew that, rather than entering the market and competing, it could make more profit by agreeing to delay entry in exchange for a portion of Kos's monopoly profits from Niaspan, paid in the form of an Exclusion Payment.

**D. In late March 2005, Kos and Barr entered into the Exclusion Payment Agreement, agreeing that Barr would not launch a generic competitor to Niaspan for more than eight years.**

83. On March 30, 2005, before the court issued a ruling on Kos's application for a preliminary injunction, Kos and Barr announced that they had settled the patent litigation and asked the court to postpone any ruling on that application so that they could formalize their settlement. The court issued a Conditional Order of Discontinuance on March 30, 2005.

84. Kos agreed to pay Barr (the alleged infringer) to settle the patent litigation in March of 2005 because Barr was ready to launch and intended to do so in April of 2005. Niaspan was too important to Kos's viability and valuation and the prospect of even an at-risk launch by Barr posed too great a threat to the pricing of Niaspan to allow generic competition; Kos needed to prevent generic entry so that it could continue to charge high prices and continue to sell high volumes of Niaspan.

85. Kos used the strength of its wallet as opposed to the strength of its patents to obtain Barr's agreement not to launch its generic version of Niaspan. Recognizing the substantial likelihood that its Niaspan patents would be invalidated and/or that the generics' products would be adjudged non-infringing, Kos agreed to share its monopoly rents with Barr as the *quid pro quo* for Barr's agreement not to compete with Kos in the extended-release niacin market until September 20, 2013.

86. Under the agreement not to compete (the “Exclusion Payment Agreement”), Kos agreed to make continuing substantial unlawful payments to Barr over a period of eight years and, in return for those payments, Barr unlawfully agreed to refrain from launching a generic equivalent of Niaspan until September 2013. That agreement preserved Niaspan’s dominant position in the market, while sharing some of the supracompetitive revenues resulting from that dominant position. Kos and Barr cloaked the payments behind a spurious supply agreement and an equally spurious promotion agreement, but the payments to Barr (and later Teva) far exceeded the fair value of any services that the generic company would provide under those agreements (including the fact that Kos did not need Barr to provide the services). The real purpose for making the payments was to induce Barr (and later Teva) to agree to delay the date on which it would begin competing with Kos’s branded Niaspan.

87. As part of the Exclusion Payment Agreement, on April 12, 2005, Kos and Barr executed three contracts that facilitated and helped effectuate their unlawful Agreement. Those three contracts were as follows:

- a. **Settlement and Licensing Agreement.** Kos and Barr agreed to drop all claims and counterclaims pending against each other in the patent lawsuits. Kos gave Barr a license for all of the patents arguably covering Niaspan on the condition that Barr would not bring a generic equivalent of Niaspan to market until September 20, 2013 (or such earlier time as may be required to preserve Barr’s right to market a generic exclusively for 180 days). Kos also agreed that it would not launch an authorized generic version of Niaspan after Barr ultimately entered the market with generic extended-release niacin even though it would make economic sense for Kos to launch an authorized generic and Kos had been planning to do so; of course, the harm to Barr from Kos’s launching of an authorized generic would have been substantial. And, Barr explicitly agreed that it would not launch a generic equivalent of Niaspan until September 20, 2013.
- b. **Co-Promotion Agreement.** For as long as Barr kept its generic equivalent of Niaspan off the market, as provided in the Settlement and Licensing Agreement, Kos agreed to pay Barr (through Duramed and DPSC, two Barr subsidiaries, which later became Teva Women’s Health, Inc.) a royalty on all

of Kos's sales of Niaspan and Advicor, another Kos drug. Barr, Duramed, and DPSC agreed to promote Niaspan and Advicor to obstetricians, gynecologists, and other doctors specializing in women's health. The royalty that Kos agreed to pay to Barr was to be based upon overall sales of Niaspan and Advicor, regardless of whether the sales were generated by Barr's sales force, and provided another incentive for Barr not to disrupt brand Niaspan sales.

- c. **License and Manufacturing Agreement.** Kos (and its subsidiary, Kos Life Sciences Inc.) made a non-refundable lump-sum payment to Barr, ostensibly as compensation for Barr's investment in developing FDA approved manufacturing processes for Niaspan and Advicor. Kos (and Kos Life Sciences Inc.) also agreed to make quarterly payments to Barr for every quarter that Barr remained ready to manufacturer Niaspan and Advicor. Barr agreed to serve as a ready back-up supplier to Kos for those products, and agreed to sell them to Kos at an agreed-upon contract price. If Barr sold a generic equivalent of Niaspan to any third-party before September 20, 2013, Kos would have no further obligation to make quarterly payments to Barr.

88. The Exclusion Payment Agreement had two other notable provisions:

- a. Kos and Barr agreed to do all things reasonably necessary to further the intent and purposes of the transactions contemplated by the Agreement.
- b. Kos and Barr agreed that either company could transfer its rights and obligations to a successor entity through a merger or other corporate takeover.

89. On April 12, 2005, and as envisioned by the Exclusion Payment Agreement, the patent court dismissed all of the patent infringement cases pending between Barr and Kos regarding Niaspan.

90. Under the Exclusion Payment Agreement, Kos (and its successors) paid Barr (and later Teva) to withhold generic Niaspan from the market until 2013. The payments have taken at least the following forms:

- a. A lump sum payment, disguised as a "stand-by" payment to compensate Barr for being ready to manufacture Niaspan under the License and Manufacturing Agreement and that has far exceeded the value that Barr (and later Teva) provided to Kos (and its successors) by being ready to manufacture and supply Niaspan;

- b. A functional equivalent of hundreds of millions of dollars in payments through forbearance by Kos (and its successors) in launching an authorized generic version of Niaspan during Barr's (and later Teva's) 180-days of exclusivity, which began on September 20, 2013, notwithstanding the facts that
  - i. Kos had been planning to launch an authorized generic when faced with Barr's impending at-risk launch in 2005; and
  - ii. It made economic sense for AbbVie to launch an authorized generic during Teva's 180-day exclusivity period (1) so that AbbVie could retain some of the sales that Teva's less expensive generic seeks to capture and (2) because AbbVie sacrificed profit by its forbearance.
- c. Quarterly payments, disguised as payments to compensate Barr (and later Teva) for remaining ready to manufacture Niaspan under the License and Manufacturing Agreement and that far exceeded the value that Barr (and later Teva) provided by remaining ready to manufacture and supply Niaspan;
- d. Quarterly royalty payments, disguised as compensation for Barr's (and later Teva's) work under the Co-Promotion Agreement and that were not legitimately tethered to and that far exceeded the value of the promotion efforts that Barr (and later Teva) was providing; and
- e. A functional equivalent of tens of millions of dollars in payments through forbearance by Kos (and its successors) in launching an authorized generic version of Advicor notwithstanding the fact that it made economic sense for AbbVie to launch an authorized generic (1) so that AbbVie could retain some of the sales that Barr's (and later Teva's) less expensive generic seeks to capture and (2) because AbbVie sacrificed profit by its forbearance.

91. All of these benefits had substantial value to Barr, and are compensation that it could not have obtained even if it had litigated and won the patent case. And these payments caused Barr to agree to stay out of the market far longer than it would have agreed to in a payment-free settlement based solely on the strength of Kos's patent claims. Kos agreed to pay and did in fact pay Barr to delay its entry into the market.

92. In the years that followed entry of the Exclusion Payment Agreement, Barr (and later Teva) continued to receive those payments, and Barr (and later Teva) continued with its

commitment that it would not launch a generic equivalent of Niaspan until September 20, 2013, more than eight years later.

93. Kos and Barr knew and intended that the Exclusion Payment Agreement would also prevent other generic companies from launching their own generic Niaspan before Barr did, thereby creating a bottleneck. As the first filer of an ANDA for a generic extended-release niacin, Barr/Teva is entitled to market its generic Niaspan for 180 days free from competition from other generic manufacturers. The operation of the parties' Exclusion Payment Agreement blocked any other generic Niaspan products from coming to market until 180 days after September 20, 2013, because the FDA would not approve any subsequently-filed ANDAs until the first-filer's exclusivity period had run, which did not occur until 180 days after Barr/Teva's actual launch.

94. But for the Exclusion Payment Agreement and the parties' ongoing adherence to and performance under that Agreement, generic competition for Niaspan would have occurred earlier and prices for both brand name Niaspan and generic extended-release niacin would have been lower. Specifically:

- a. Had Barr/Teva launched a generic equivalent of Niaspan at any time prior to September 20, 2013, the generic equivalent would have sold at lower prices than the prices at which Kos/Abbott/AbbVie was selling Niaspan. Plaintiffs would have paid lower prices for extended-release niacin than they actually paid.
- b. Had Kos/Abbott/AbbVie launched its authorized generic equivalent of Niaspan when Barr/Teva launched, prices would have dropped even lower. As a matter of pharmaceutical economics, prices fall most dramatically when two or more generic equivalents of a drug are on the market alongside a brand name product. The Exclusion Payment Agreement prevented that generic competition from occurring and kept prices higher for Plaintiffs.
- c. Had Barr launched earlier at risk, via settlement, or after victory in the patent litigation, other generic manufacturers would have been able to launch their own generic equivalents of Niaspan 181 days after Barr's



launch, following the lapse of Barr's 180-day exclusivity period. By delaying Barr's launch until September 20, 2013, Kos and Barr sought to prevent - and succeeded in preventing - other generic manufacturers from launching until 2014.

95. The purpose and effect of the Exclusion Payment Agreement was to suppress generic competition and to allow Kos/Abbott/AbbVie to charge supracompetitive prices for Niaspan without losing significant sales.

96. Kos/Abbott/AbbVie's payments to Barr/Teva under this agreement have been substantial, and those payments have continued to involve significant sums, including the following:

- a. In 2005, Kos paid Barr an "upfront fee" believed to be approximately \$5 million (and supplemented by future "stand ready" quarterly fees) upon signing the settlement agreement in exchange for Barr's commitment to stand by as an alternate supply source for Niaspan.
- b. In 2006, Kos paid Barr approximately \$45 million in royalty payments based on Kos's sales of Niaspan and Advicor, which was the "maximum annual royalty" the Exclusion Payment Agreement contemplated for the year.
- c. In 2007, Kos paid Barr approximately \$37 million, again the maximum annual royalty amount for that year under their co-promotion agreement for the sales of Niaspan and Advicor. On information and belief, Kos/Abbott/AbbVie have made similar payments in subsequent years and paid Barr/Teva millions of dollars more than they otherwise would have paid for any services allegedly performed or to be performed under the Exclusion Payment Agreement.
- d. Kos/Abbott/AbbVie refrained from introducing an authorized generic version of Niaspan in September 2013 when Barr/Teva finally launched its generic product, permitting Barr/Teva to earn millions of dollars in additional revenues as the sole generic product on the market.
- e. Kos gave Barr an opportunity to earn royalties on Kos's sales of its brand name Advicor prior to entry of a generic version to that product, even though Advicor had not been a part of the patent dispute that was being settled. The Advicor portion of the Exclusion Payment Agreement mirrored the Kos/Barr deal concerning Niaspan and constituted further payment to Barr for delaying the launch of generic Niaspan. Kos paid Barr millions of



dollars more than it otherwise would have paid for any services allegedly performed or to be performed under the Exclusion Payment Agreement.

- f. On information and belief, long after the Exclusion Payment Agreement was assigned following multiple corporate transactions, Kos/Abbott/AbbVie continued to pay Barr/Teva millions of dollars every year, and those payments were still occurring in 2013.

97. Consistent with the Exclusion Payment Agreement, Kos and Barr took steps to fraudulently conceal their unlawful agreement to suppress generic competition.<sup>1</sup>

98. When the Exclusion Payment Agreement was announced, both Kos and Barr repeatedly stated that the effect of the agreement was to bring a generic equivalent of Niaspan to the market in 2013, which they asserted was four years earlier than the expiration date of the last of Kos's patents ostensibly covering Niaspan. These statements were false and misleading, and both companies knew that they were false and misleading. The statements ignored the fact that Barr would have launched a generic equivalent of Niaspan at risk in April of 2005. Thus, when Kos and Barr proclaimed that the Exclusion Payment Agreement would bring generic equivalents of Niaspan to market sooner than they otherwise would have arrived, both companies knew that the real purpose and effect of the Exclusion Payment Agreement was to delay generic entry for many years.

99. When the Exclusion Payment Agreement was announced, Kos and Barr both refused to disclose the amount of the payments provided under the Agreement, because they had agreed to conceal the amounts of the payments that Barr was receiving. Repeatedly, when Wall Street analysts asked either company to disclose the amounts of the payments (or even the details

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<sup>1</sup> The allegations in paragraphs 97 through 102 are included solely to preserve Plaintiffs' appellate rights. Plaintiffs understand that the Court has dismissed similar allegations of fraudulent concealment in other cases pending as part of MDL Docket No. 2460 and do not dispute that the Court would reach the same result in this case.

for how the amounts would be calculated), the companies refused. Indeed, during conference calls with investment bank analysts, Kos representatives refused to answer direct questions from analysts in the financial community who asked about the financial terms of the payments that Kos was making to Barr (including an April 13, 2005 Conference Call, in which Barr's Chief Executive Officer Bruce Downey refused to provide details when asked about the financial terms of the Agreement, and an August 4, 2005 Conference Call, in which Kos's Interim Chief Financial Officer Juan Rodriguez refused to provide details of those financial terms).

100. Kos filed copies of contracts dated April 12, 2005 with the Securities and Exchange Commission as part of its 10-Q filing dated August 9, 2005, but the publicly filed versions of those contracts redacted the financial terms regarding the payments. Neither company reported the amounts of the payments as separate items in their financial reports. Additionally, the publicly-filed versions of the contracts contained recital clauses that falsely stated that the parties were hastening the entry of a generic equivalent of Niaspan, when in fact the parties had agreed to delay generic entry for many years.

101. Because the alleged conspiracy was both self-concealing and material facts were affirmatively concealed and misrepresented by the defendants and their co-conspirators, Plaintiffs had no knowledge of the alleged conspiracy, or of facts or information that would have caused a reasonably diligent person to investigate whether a conspiracy existed.

102. As a result of Defendants' fraudulent concealment, all applicable statutes of limitations affecting Plaintiffs' claims have been tolled until a date less than four years prior to the filing of the first class action on behalf of direct purchasers of Niaspan.

**E. The FDA granted final approval to Barr on April 26, 2005, days after Kos and Barr entered the Exclusion Payment Agreement.**

103. On April 26, 2005, shortly after the Exclusion Payment Agreement was signed, Barr received the clearance from the FDA that it had been expecting: the FDA granted final approval to Barr to manufacture and market generic Niaspan.

104. At the same time, given the existence of the Exclusion Payment Agreement, Barr disposed of the inventory that it had accumulated to be ready for its generic launch and took an inventory write-down in connection with its decision not to launch in April of 2005. Kos did the same thing for its inventory of an authorized generic version of Niaspan. (Kos had accumulated that inventory prior to the Exclusion Payment Agreement, on the expectation that it would begin selling an authorized generic Niaspan product to compete with Barr's generic Niaspan product as soon as Barr launched).

**F. Abbott acquired Kos and continued the unlawful agreement to suppress generic competition.**

105. In November of 2006, Abbott proposed to acquire control of Kos through a tender offer transaction. Abbott offered to pay Kos shareholders \$78 per share, a 56% premium on the open-market share price of \$50 per share. At the time of the offer, Kos's portfolio of products was still heavily dependent on Niaspan, and Kos had few products in development. Thus, Niaspan (and the unlawful and ongoing Exclusion Payment Agreement preventing generic competition to it) was a central element of Abbott's valuation of Kos's business. Had generic versions of Niaspan entered the market prior to November 2006, Abbott would have not been willing to pay nearly as much as it ultimately paid for Kos.

106. Abbott's tender offer was successful, and Kos was merged into Abbott in December of 2006. As Kos's successor, Abbott stepped into the shoes of Kos with respect to the ongoing unlawful Exclusion Payment Agreement with Barr. Barr continued to refrain from

entering the market with a generic equivalent of Niaspan, staying off the market until the agreed upon launch date on September 20, 2013, and Abbott continued to make the agreed-upon payments to Barr. In this way, both parties continued with the unlawful Exclusion Payment Agreement that suppressed generic competition for Niaspan.

107. In addition to succeeding to Kos's liability, Abbott joined the ongoing unlawful course of conduct and conspiracy to suppress generic competition to Niaspan. Abbott did not withdraw from that conspiracy and instead continued to participate in and take affirmative steps to perpetuate it.

108. To the extent that the Exclusion Payment Agreement had any minimal value to Kos in the form of co-promotion services or backup supply arrangements, those considerations had even less value to Abbott: Abbott was a substantially larger enterprise than Kos was, had an even larger promotion force, and had no use for additional supply capacity. The Exclusion Payment Agreement was valuable to Abbott because the Agreement was postponing Barr's launch of a generic equivalent of Niaspan, and Abbott was willing to continue to pay Barr for that ongoing suppression of generic competition.

109. Because it was substantially larger, Abbott was better able to exploit the market advantages created by the ongoing unlawful Exclusion Payment Agreement to suppress generic competition. After Abbott took over the Niaspan business, sales of Niaspan increased significantly. Annual U.S. retail sales of Niaspan more than doubled between 2006 and 2012, from \$474 million to \$1.03 billion.

**G. Teva acquired Barr and continued the unlawful agreement to suppress generic competition.**

110. On December 23, 2008, Barr became a wholly-owned subsidiary of Teva. Teva continued to follow the ongoing unlawful Exclusion Payment Agreement then in place with

Abbott. Teva continued to refrain from entering the market with a generic equivalent of Niaspan, agreeing to hold off until September 20, 2013, and Abbott continued to make the agreed-upon payments to Teva.

111. Because of the acquisition, Teva also owned (either directly or indirectly) Barr's first-filer rights. Accordingly, no other generic company was able to launch a generic equivalent of Niaspan until Teva's 180-day period as the exclusive generic seller of extended-release niacin expired. Following Teva's launch of a generic equivalent of Niaspan on September 20, 2013, no other generic manufacturer was permitted to introduce a generic equivalent of Niaspan until March 2014.

112. In addition to succeeding to Barr's liability, Teva joined the ongoing unlawful course of conduct and conspiracy to suppress generic competition to Niaspan. Teva did not withdraw from that conspiracy and instead continued to participate in it.

**H. Abbott acted to preserve the unlawful agreement to suppress generic competition.**

113. Between 2006 and 2012, Abbott took additional steps to ensure that nothing happened to disrupt the Exclusion Payment Agreement or allow generic competition for Niaspan before September of 2013.

114. For example, Abbott knew that if any other generic drug manufacturer obtained a final judgment following a court decision of invalidity, unenforceability, or non-infringement of the Niaspan patents, then Teva's 180-day exclusivity period would begin to run. Teva would be motivated to launch its generic product immediately, before the agreed-upon launch date of September 20, 2013, cutting short the defendants' unlawful scheme. Recognizing this risk, Abbott acted aggressively to prevent such a disruption.

115. On March 6, 2009, Abbott filed a patent infringement lawsuit against Lupin Limited in the United States District Court for Delaware (docketed as 09-cv-152). Abbott alleged that Lupin, a generic manufacturer, had infringed Abbott's patents by filing a Paragraph IV certification as part of an effort to gain approval for and launch a generic equivalent of Niaspan. On June 13, 2012, Abbott and Lupin stipulated to a dismissal of the lawsuit. The court never ruled on whether Lupin had infringed Abbott's patents or issued any final judgment on Lupin's claims that Abbott's patents were invalid or unenforceable.

116. After March 2009, Abbott filed numerous additional patent infringement lawsuits against generic manufacturers that had filed Paragraph IV certifications with respect to a possible generic equivalent of Niaspan. Abbott (later AbbVie) settled six of those cases and dismissed them by stipulation, with no final judgments entered on the infringement, validity, or enforceability of Abbott/AbbVie's patents.

- a. In *Abbott Laboratories v. Sun Pharmaceuticals Indus. Ltd.*, No. 10-CV-112 (D. Del.), the court scheduled trial for mid-2013 but the parties settled in February 2013, before the court issued any substantive rulings;
- b. In *Abbott Laboratories v. Sandoz, Inc.*, No. 1 O-CV-538 (D. Del.), the parties settled in March 2013, one month before trial, and again before the court issued any substantive rulings;
- c. In *Abbott Laboratories v. Amneal Pharmaceuticals LLC*, No. 12-CV-235 (D. Del.), the parties settled in March 2013, before the court issued any substantive rulings;
- d. In *Abbott Laboratories v. Cadila Healthcare Ltd.*, No. 12-CV-0065 (D. Del.), the parties settled on August 14, 2013, before the court issued any substantive rulings;
- e. In *Abbott Laboratories v. Kremers Urban Pharmaceuticals, Inc.*, No. 12-CV-703 (D. Del.), the parties settled on September 26, 2013 before the court issued any substantive rulings;

- f. In *Abbott Laboratories v. Watson Laboratories, Inc.*, No. 12-CV-324 (D. Del.), the parties settled on September 12, 2013 before the court issued any substantive rulings; and
- g. In *Abbott Laboratories v. Mylan Pharmaceuticals, Inc.*, No. 12-CV-257 (D. Del.), the parties settled on February 4, 2014 before the court issued any substantive rulings.

117. In pursuing and settling these lawsuits, Abbott/AbbVie has been able to avoid the entry of any definitive ruling that would have accelerated the date for the 180-day exclusivity for Teva. Through delay and through settlements, Abbott/AbbVie has ensured that no final judgment has been entered on non-infringement, invalidity, or unenforceability of the relevant patents.

118. Abbott/AbbVie has prosecuted these patent cases as part of its covenant to take steps necessary to preserve the agreement to suppress generic competition, as part of the Exclusion Payment Agreement. Abbott/AbbVie's conduct in these lawsuits is part of and in furtherance of its ongoing unlawful agreement with Teva to suppress generic competition in the market for Niaspan.

**I. Abbott spun off Niaspan to AbbVie and AbbVie continued with the unlawful agreement to suppress generic competition.**

119. In 2012, Abbott announced that it was spinning off most of its prescription drug business into a new company, AbbVie. That spin-off became effective as of January 1, 2013. As Abbott's successor, AbbVie has stepped into the shoes of Abbott with respect to the ongoing unlawful Exclusion Payment Agreement with Teva. Teva continued to refrain from launching a generic equivalent of Niaspan until September 20, 2013 and AbbVie has continued to make the agreed-upon payments to Teva.

120. Upon the transition of the Niaspan business from Abbott to AbbVie on or about on January 1, 2013, AbbVie joined the ongoing unlawful course of conduct and conspiracy to



suppress generic competition to Niaspan. AbbVie did not withdraw from that conspiracy and instead continued to participate in it.

**J. The unlawful agreement to suppress generic competition continues to cause injury.**

121. Until September 20, 2013, no generic equivalent of Niaspan was on the market in the United States. When Teva finally began selling generic Niaspan, AbbVie adhered to its agreement not to launch an authorized generic. With only one generic product on the market, Plaintiffs were denied the lower prices that full generic competition would have brought to the market. This lack of full generic competition was the direct result of the ongoing unlawful Exclusion Payment Agreement (and the subsequent settlements with other generic competitors) that will continue to dampen competition at least through the end of 2015.

122. The unlawful agreement has resulted in higher prices for Teva's extended release niacin. Since September of 2013, when Teva began selling generic Niaspan, Teva has been able to charge higher prices than those it would have been able to charge but for AbbVie's promise not to launch an authorized generic of Niaspan. Thus, Teva has been able to launch and sell its generic at a higher price than it otherwise would have without competitive pressure from an authorized generic version of Niaspan during the most lucrative time immediately following Teva's launch.

123. During the entire four-year period prior to the filing of the first direct purchaser class complaint, Defendants' unlawful conduct and violation of the antitrust laws was ongoing, payments were being made from Abbott and AbbVie to Teva to compensate Teva for refraining from entering the market with generic Niaspan prior to September 20, 2013, and Plaintiffs (or their assignors) continued to suffer injury with every purchase and on every day that Defendants' unlawful Exclusion Payment Agreement not to compete remained in place. During the applicable

limitations period, Defendants operated under an ongoing Exclusion Payment Agreement to suppress generic competition, and Plaintiffs were injured by Defendants' ongoing conduct.

**K. The unlawful agreement to suppress generic competition harms competition, injures plaintiffs, and causes damages.**

124. On May 9, 2003, the FDA issued tentative approval for Barr's ANDA for a generic equivalent of the 1000 mg dosage of Niaspan. On June 13, 2003, the FDA issued tentative approval for Barr's ANDA for a generic equivalent of the 500 mg and 750 mg dosages of Niaspan. The FDA issues tentative approval only when it determines that an ANDA would otherwise be ready for final approval but for a thirty-month stay.

125. But for Defendants' overarching, anticompetitive, and ongoing scheme to delay generic Niaspan competition in the United States, a generic equivalent of Niaspan would have been available in the United States far earlier than September 20, 2013, the first date that generic Niaspan actually became available.

126. Additionally, but for the illegal conduct described in the complaint, Kos would have launched its own authorized generic Niaspan product at the same time that Barr launched its extended-release niacin, resulting in additional price competition for Niaspan and its generic equivalents during Barr's 180-day exclusivity period.

127. But for the anticompetitive and illegal conduct alleged in this complaint, Plaintiffs would have saved hundreds of millions of dollars on their purchases of extended-release niacin.

128. The active ingredient in Niaspan is extended-release niacin. Its pharmacological profile, and thus its side effect and efficacy profile, are different from other prescription and nonprescription medicines that are used to treat the same or similar conditions. Those other drugs are not AB-rated to Niaspan, cannot be automatically substituted for Niaspan by pharmacists, do

not exhibit substantial cross-price elasticity of demand with respect to Niaspan, and thus are not economic substitutes for, nor reasonably interchangeable with, Niaspan.

129. Defendants' unlawful Exclusion Payment Agreement was designed to and did in fact: (a) preclude the entry of less expensive generic versions of extended-release niacin in the United States; (b) fix, raise, maintain or stabilize the prices of extended-release niacin products; (c) permit Kos/Abbott/AbbVie to maintain a monopoly in the United States for extended-release niacin; (d) allocate 100% of the United States extended-release niacin market to Kos/Abbott/AbbVie until September 20, 2013; and (e) allocate 100% of the United States generic extended-release niacin market to Barr/Teva for the six months beginning on September 20, 2013.

130. Defendants violated sections 1 and 2 of the Sherman Act through their conspiracy to improperly maintain and extend their market and monopoly power by foreclosing or delaying competition from lower-priced generic versions of extended-release niacin.

## **VI. ANTICOMPETITIVE EFFECTS OF DEFENDANTS' SCHEME**

131. Defendants' scheme and payments to suppress generic competition to Niaspan significantly delayed the sale of generic Niaspan. But for Defendants' unlawful conduct, a generic version of Niaspan would have been available for purchase well before September 20, 2013.

132. The generic manufacturers seeking to sell generic Niaspan have extensive experience in the pharmaceutical industry, including in obtaining approvals for ANDAs, marketing generic pharmaceutical products, manufacturing commercial quantities adequate to meet market demand, and, where appropriate, entering into arrangements with other generic manufacturers to waive or relinquish 180-day exclusivity in order to bring generic drugs to market in a timely manner.

133. Defendants' overarching anticompetitive scheme unlawfully enabled Kos/Abbott/AbbVie to sell Niaspan free of generic competition and at artificially inflated prices. But for Defendants' illegal conduct, generic manufacturers would have been able to enter the market and compete on the merits against Niaspan. Defendants' conduct unlawfully prevented purchasers of Niaspan from obtaining the benefits of unimpaired generic competition.

134. Defendants' scheme and unlawful payments harmed Plaintiffs by depriving them of a competitive market in which decisions about challenging patents and launching lower-priced generic drugs are not influenced by large and unjustified reverse payments.

135. But for the anticompetitive scheme: (i) Barr would have begun selling AB-rated generic versions of Niaspan well before September 20, 2013; (ii) Kos/Abbott/AbbVie would have launched an authorized generic simultaneously with Barr's launch; and (iii) one or more additional generic competitors would have launched their products upon the expiration of Barr's 180-day exclusivity.

136. Defendants' unlawful conduct has delayed the sale of generic Niaspan in the United States, and unlawfully enabled Kos/Abbott/AbbVie to sell Niaspan at artificially inflated, supracompetitive prices without losing sales to generic competitors. Defendants' conduct also allowed Teva to sell generic Niaspan at artificially inflated prices because of the absence of competition from an authorized generic.

137. As a consequence, Plaintiffs have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

## **VII. INTERSTATE COMMERCE**

138. The drugs at issue in this case are sold in interstate commerce. Defendants' unlawful activities, as alleged above, have occurred in, and have had a substantial impact on, interstate commerce.

## **VIII. MARKET POWER AND MARKET DEFINITION**

139. At all relevant times, Kos/Abbott/AbbVie had market power with respect to extended-release niacin because it had the power to raise and/or maintain the price of the drug at supracompetitive levels without losing substantial sales.

140. A small but significant, non-transitory price increase above the competitive level for Niaspan by Kos/Abbott/AbbVie would not have caused a significant loss of sales sufficient to make the price increase unprofitable.

141. At competitive price levels, Niaspan does not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than AB-rated generic versions of Niaspan.

142. The 2011 AIM-HIGH study published in the New England Journal of Medicine found that extended-release niacin did not prevent heart attacks in patients whose cholesterol was controlled with a statin. This negative published study resulted in a significant decline in demand for Niaspan. However, Abbott and AbbVie were able to offset the decline in demand by raising the price of Niaspan approximately 37% without experiencing any additional loss in sales—something they could not do without monopoly power.

143. For clinical reasons, among others, physicians and patients prefer Niaspan to other products designed to treat lipid disorders.

144. The existence of other products designed to treat similar disorders has not significantly constrained Kos/Abbott/AbbVie's pricing of Niaspan. At all relevant times,

Kos/Abbott/AbbVie's price for Niaspan has been substantially above its marginal cost of production, and substantially above its marginal cost including marketing costs. Kos/Abbott/AbbVie has never lowered the price of Niaspan in response to the pricing of other cholesterol treatments (or the launch of generic versions of those other treatments).

145. Kos/Abbott/AbbVie needed to control only Niaspan and its AB-rated generic equivalents, and no other products, in order to maintain the price of Niaspan profitably at supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Niaspan would render Kos/Abbott/AbbVie unable to profitably maintain supracompetitive prices for Niaspan.

146. Kos/Abbott/AbbVie knew that entry of a generic version of Niaspan would be a uniquely significant market event. The entry of other branded drugs in the same therapeutic class (or generic versions of those other brands) did not take substantial sales from Niaspan or cause Kos/Abbott/AbbVie to lower its price. But Kos/Abbott/AbbVie predicted that entry of generic Niaspan would immediately cause branded Niaspan to lose well more than half of its unit sales. Likewise, Barr estimated that its generic version of Niaspan would take essentially all of its sales from branded Niaspan and few if any sales from other branded drugs (or generic versions of those other brands).

147. At all relevant times, Kos/Abbott/AbbVie has sold Niaspan at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

148. Kos/Abbott/AbbVie had, and exercised, the power to exclude and restrict competition in the market for Niaspan and its AB-rated generic equivalents.

149. Kos/Abbott/AbbVie, at all relevant times, enjoyed high barriers to entry with respect to competition in the relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

150. To the extent that Plaintiffs are legally required to prove market power circumstantially by first defining a relevant product market, Plaintiffs allege that the relevant product market is extended-release niacin (*i.e.*, Niaspan and its AB-rated generic equivalents). During the relevant time, Kos/Abbott/AbbVie has been able to profitably maintain the price of extended-release niacin well above competitive levels.

151. The relevant geographic market is the United States and its territories.

152. Until September 2013, Kos/Abbott/AbbVie's market share in the relevant market was 100%, implying a substantial amount of market power.

#### **IX. EFFECT ON COMPETITION AND INJURY TO PLAINTIFFS**

153. Defendants' anticompetitive conduct had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Niaspan from generic competition.

154. Defendants' anticompetitive conduct, which delayed introduction into the United States marketplace of generic versions of Niaspan, has caused Plaintiffs and/or their assignors to pay more than they would have paid for extended-release niacin absent Defendants' illegal conduct.

155. But for Defendants' anticompetitive conduct, Plaintiffs and/or their assignors would have paid less for extended-release niacin by: (a) substituting purchases of less-expensive AB-rated generic Niaspan for their purchases of more-expensive branded Niaspan; and (b) purchasing generic Niaspan at lower prices sooner.



156. Plaintiffs and/or their assignors purchased substantial amounts of Niaspan. As a result of Defendants' illegal conduct as alleged herein, Plaintiffs and/or their assignors were compelled to pay, and did pay, artificially inflated prices for extended-release niacin. Plaintiffs and/or their assignors paid prices for extended-release niacin that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein.

157. Plaintiffs' injuries are injuries of the type the antitrust laws were designed to prevent and flow from that which makes Defendants' acts unlawful.

158. Defendants' unlawful conduct threatens continuing loss and injury to Plaintiffs unless enjoined by this Court.

## **X. CLAIMS FOR RELIEF**

### **Claim I: Violation of 15 U.S.C. § 2 Monopolization (Overall Scheme) (Asserted Against Abbott/AbbVie)**

159. Plaintiffs incorporate by reference the allegations in paragraphs 1 through 158 above as though fully set forth herein. This claim is asserted against Defendants Abbott and AbbVie.

160. At all relevant times, Kos/Abbott/AbbVie possessed substantial market power (i.e., monopoly power) in the relevant market. Kos/Abbott/AbbVie possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

161. Through its overarching anticompetitive scheme, as alleged above, Kos/Abbott/AbbVie willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen, and thereby injured Plaintiffs. Such conduct includes entering into the unlawful Exclusion Payment Agreement with Barr and continuing to adhere to that Agreement thereafter.

Kos/Abbott/AbbVie's conduct was designed to delay the introduction of generic formulations of Niaspan into the market.

162. It was Kos/Abbott/AbbVie's conscious object to further its dominance in the relevant market by and through the overarching anticompetitive scheme.

163. Kos/Abbott/AbbVie's scheme harmed competition.

164. There is and was no cognizable, non-pretextual procompetitive justification for Kos/Abbott/AbbVie's actions that outweighs the scheme's harmful effects. Even if there were some conceivable justification that Kos/Abbott/AbbVie were permitted to assert, the scheme is and was broader than necessary to achieve such a purpose.

165. As a direct and proximate result of Kos/Abbott/AbbVie's illegal and monopolistic conduct, as alleged herein, Plaintiffs and/or their assignors suffered injury to their business and property.

**Claim II: Violation of 15 U.S.C. § 2  
Attempt to Monopolize  
(Asserted Against Abbott/AbbVie)**

166. Plaintiffs incorporate by reference the allegations in paragraphs 1 through 158 above as though fully set forth herein. This claim is asserted against Defendants Abbott and AbbVie.

167. Kos/Abbott/AbbVie, through its overarching anticompetitive scheme, specifically intended to maintain monopoly power in the relevant market. It was Kos/Abbott/AbbVie's conscious objective to control prices and/or to exclude competition in the relevant market.

168. The natural and probable consequence of Kos/Abbott/AbbVie's overarching anticompetitive scheme, which was intended by it and plainly foreseeable to it, was to control prices and exclude competition in the relevant market.

169. There was a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that Kos/Abbott/AbbVie will succeed in and achieve its goal of maintaining monopoly power in the relevant market.

170. As a direct and proximate result of Kos/Abbott/AbbVie's illegal and monopolistic conduct, Plaintiffs and/or their assignors suffered injury to their business and property.

**Claim III: Violation of 15 U.S.C. § 1  
Conspiracy in Restraint of Trade  
(Asserted Against All Defendants)**

171. Plaintiffs incorporate by reference the allegations in paragraphs 1 through 158 above as though fully set forth herein.

172. The Exclusion Payment Agreement between Kos/Abbott/AbbVie and Barr/Teva involved: (a) a large and unjustified payment from Kos/Abbott/AbbVie to Barr/Teva; and (b) an agreement by Barr/Teva to delay marketing its generic Niaspan until September 20, 2013 (or earlier in certain circumstances). The payments from Kos/Abbott/AbbVie to Barr/Teva under the Agreement were the *quid pro quo* for Watson's agreement to delay marketing its generic version of Niaspan for many years. Absent the payments, Watson would not have agreed to delay marketing its generic version of Niaspan until 2013. In addition, the Exclusion Payment Agreement is a *per se* unlawful horizontal market allocation agreement that divides the relevant market temporally rather than geographically.

173. The purpose and effect of the unlawful Exclusion Payment Agreement was to allocate 100% of the United States market for extended-release niacin to Kos/Abbott/AbbVie; delay the sales of generic Niaspan products for up to eight years; allocate 100% of the United States market for generic extended-release niacin to Barr/Teva for six months after Barr/Teva ultimately launched generic Niacin; and fix the price which Plaintiffs and/or their assignors would pay for extended-release niacin at the higher, branded price.

174. The Exclusion Payment Agreement constitutes a continuing contract, combination and conspiracy in restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. The Exclusion Payment Agreement is both a reverse-payment settlement agreement and a *per se* unlawful horizontal market allocation. The purpose and effect of the payments flowing from Kos/Abbott/AbbVie to Barr/Teva under the Exclusion Payment Agreement was to delay generic competition to Niaspan and there is no legitimate, nonpretextual, procompetitive business justification for the payment that outweighs its harmful effect. Even if there were some such conceivable justification, the payment was not necessary to achieve such a purpose.

175. At all relevant times, Kos/Abbott/AbbVie possessed market power in the relevant market. Kos/Abbott/AbbVie possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

176. The goal, purpose and/or effect of the Exclusion Payment Agreement was to prevent and/or delay generic competition to Niaspan and enable Kos/Abbott/AbbVie to continue charging supracompetitive prices for Niaspan without a substantial loss of sales. By means of the Kos/Abbott/AbbVie's payment to Barr/Teva, Defendants shared the supracompetitive profits that their unlawful agreement made possible.

177. As a direct and proximate result of Defendants' unlawful conspiracy in restraint of trade, Plaintiffs and/or their assignors have suffered injury to their business and property.

**Claim IV: Violation of 15 U.S.C. § 2  
Conspiracy to Monopolize  
(Asserted Against All Defendants)**

178. Plaintiffs incorporate by reference the allegations in paragraphs 1 through 158 above as though fully set forth herein.

179. At all relevant times, Kos/Abbott/AbbVie possessed substantial market power (i.e., monopoly power) in the relevant market. Kos/Abbott/AbbVie possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

180. Through the Exclusion Payment Agreement with Barr/Teva, Kos/Abbott/AbbVie conspired with Barr/Teva to maintain monopoly power in the relevant market by preventing and delaying the entry of a competing AB-rated generic version of Niaspan. The unlawful Exclusion Payment Agreement allocated all sales of extended-release niacin in the United States to Kos/Abbott/AbbVie; delayed the sale of less expensive generic extended-release niacin; allocated all sales of generic extended-release niacin in the United States to Barr/Teva for six months after Barr/Teva ultimately launched generic Niaspan; and fixed the price at which Plaintiffs would purchase extended-release niacin at the higher, brand-name price.

181. The goal, purpose and effect of the Exclusion Payment Agreement was to maintain Kos's monopoly power in the United States for extended-release niacin in violation of section 2 of the Sherman Act, 15 U.S.C. § 2. The Exclusion Payment Agreement prevented and delayed generic competition to Niaspan and enabled Kos/Abbott/AbbVie to continue charging supracompetitive prices for the drug without a substantial loss of sales.

182. Kos and Bar knowingly and intentionally conspired to maintain Kos's monopoly power in the relevant market.

183. Kos and Barr specifically intended that the Exclusion Payment Agreement would maintain Kos's monopoly power in the relevant market, and injured Plaintiffs thereby.

184. Kos and Barr each committed numerous overt acts in furtherance of the conspiracy.

185. As a direct and proximate result of Defendants' conspiracy to monopolize, Plaintiffs and/or their assignors suffered injury to their business and property.

### **XI. DEMAND FOR JUDGMENT**

WHEREFORE, Plaintiffs pray for judgment against Defendants and for the following relief:

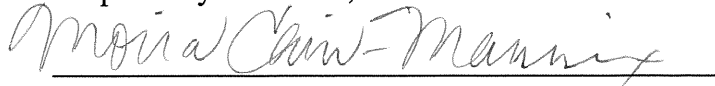
- A. A declaration that the conduct alleged herein is in violation of Sections 1 and 2 of the Sherman Act;
- B. A permanent injunction enjoining Defendants from continuing their illegal conduct and requiring them to take affirmative steps to dissipate the continuing effects of their prior conduct;
- C. An award of Plaintiffs' overcharge damages, in an amount to be determined at trial, trebled;
- D. An award of Plaintiffs' costs of suit, including reasonable attorneys' fees as provided by law; and
- E. Such other and further relief as the Court deems just and proper.

### **XII. JURY DEMAND**

Plaintiffs demand a trial by jury of all issues so triable.

Dated: March 5, 2015

Respectfully submitted,



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